

Terrestrial Animal Health Report – March 2006
USA Comments

The following are general comments and recommendations on the proposed draft Appendix 3.8.5 titled “Factors to Consider in Conducting the BSE Risk Assessment Recommended in Chapter 2.3.13”.

After reviewing the proposed appendix, it is not completely clear if these factors for consideration are intended to be used for countries to conduct their own internal assessment, or for importing countries to conduct an assessment of exported countries, or for the OIE to conduct an evaluation of country status. As written, they appear to be a draft of a questionnaire which the OIE developed for country status evaluation. They do not appear to be written to guide a country to conduct its own internal assessment.

Guidance should be given on how to realistically consider the possibilities of release and/or exposure. As drafted, the document asks for an extensive amount of “documentation”, however, no guidance is provided on how to evaluate this documentation that would help reach a conclusion about either release or exposure. While identifying what “documentation” may be necessary is important to reach a conclusion, how that conclusion is reached in a realistic manner is the challenging part of this process.

We believe that much clarity would be given to the proposed document if its *Articles* of the Appendix were structured to logically follow through the sequence of release and exposure assessments. Below is a suggested outline with the relevant *Article* from the current proposed draft Appendix identified following each point:

1) Release assessment:

- (1) Possible release through imports
 - (a) imports of live ruminants (*Article 3.8.5.3*)
 - (b) imports of rendered protein, or animal feed containing rendered protein (*Article 3.8.5.2*)
 - (c) imports of other ruminant products (either for human consumption or other use) that may contain SRMs (*Article 3.8.5.4*)
 - (d) imports of veterinary biologicals/pharmaceuticals for in vivo ruminant use (*Article 3.8.5.6*)
- (2) Possible release through the existing presence of the agent in the native cattle population (*Article 3.8.5.1 ?*)

- 2) **Exposure assessment:** (Note: ideally an exposure assessment is only done if the release assessment demonstrates the possibility of release. If there is no possibility of release, then the exposure assessment is not truly necessary.)
- 3)
- (1) Direct exposure from imported feed/rendered protein - this would consider whether a feed ban is in place to prevent exposure from occurring. It would also consider whether management practices (i.e. no intensive production, only grass-fed) preclude such exposure – although this would be unlikely if imports of rendered protein are occurring (i.e., why import a protein product if there is no use for it in a local production situation) (*Article 3.8.5.5*)
 - (2) Secondary exposure – i.e., spread to native animals from release via infected imported animals or animals directly exposed via imported feed - the first step in the pathway is whether a local rendering industry exists. If no such industry exists, then the secondary exposure assessment can stop as there would be no route for amplification and spread without a rendering industry. If a rendering industry does exist, then continue with the relevant questions about processes used, components of ruminant feed, feed ban regulations in place and their enforcement, etc.... (*Article 3.8.5.7*)
- 4) **Surveillance --** to document whether release and/or exposure has occurred or is continuing (*Article 3.8.5.1*)